REMARKS

Claims 1-17 are pending in the instant application. Claims 6, 10-14, 16 and 17 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-5, 7-9 and 15 have been rejected. Claim 1 and 15 have been amended. New claims 18 through 25 have been added. Support for these amendments is provided in the specification at page 14, line 17 through page 16, line 30, page 32, line 12 through page 33, line 16, Example 1 and claim 1. Thus no new matter is added by these amendments. Reconsideration is respectfully requested in light so these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed September 4, 2003. Thus, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice non-elected claims 6, 10-14, 16 and 17. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Claims

Claims 1-5, 7-9 and 15 have been objected to as reciting non-elected subject matter. Accordingly, in an earnest effort to advance the prosecution of this case. Applicants have amended these claims to be drawn to the elected sequence, SEQ ID NO:43, its related sequence, SEQ ID NO:42, and SEQ ID NO:96, encoded thereby. Withdrawal of this objection is therefore respectfully requested.

III. Objection to the Specification

The specification has been objected to. In particular, the Examiner suggests that the underscore at page 75, line 20 in the phrase "yeast_mating factor" should be deleted.

Further, the Examiner suggests that the embedded hyperlinks and/or other forms of browser executable code in the specification must be deleted.

Further the Examiner suggests that the title is not descriptive.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the title of the application to be more descriptive. Further, Applicants have replaced the underscore in the phrase "yeast_mating factor" with

an --α-- symbol in accordance with this well known term of art. Finally, Application have amended the specification to inactivate any embedded hyperlinks and/or other forms of browser executable code in the specification. Amendments to correct inadvertent typographical errors noted in the specification during review for the above issues were also made.

No new matter is added by any of these amendments to the specification.

Withdrawal of all objections to the specification is respectfully requested in light of these amendments.

IV. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, second paragraph

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the Examiner suggests that the phrase "selectively hybridizes" is not clear.

The claims are also suggested to be indefinite over claim 1(d) because the Examiner suggests that it is not clear as to how "a nucleic acid molecule having at least 60% sequence identity of

(a) or (b) can encode an amino acid sequence of SEQ ID NO:96."

Thus, in an earnest effort to advance the prosecution of this case and in accordance with the Examiner's suggestion, Applicants have amended the specification to recite hybridization conditions. Support for this amendment is provided in the specification at page 14, line 17 though page 16, line 30.

Further, Applicants have amended part (d) of claim 1 in accordance with teachings at page 32-33 of the specification to state that the nucleic acid molecule has at least 90% sequence identity over its entire length to the nucleic acid molecule of (a) or (b). Degeneracy of the genetic code is well understood by those skilled in the art and it is reasonable to expect a sequence with 90% identity or higher to the reference sequence to encode the same amino acid sequence as the reference sequence.

Thus, the claims as amended are clear and definite to one skilled in the art, thus meeting the requirements of 35 U.S.C. § 112, first paragraph, as set forth in MPEP § 2173.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph is therefore respectfully requested.

V. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 101 as the Examiner suggests that the claimed invention is not supported by either a substantial asserted utility, or a well established utility. The Examiner has acknowledged the specification to identify SEQ ID NO:42 and 43 as a CLASP 5 candidate differentially expressed in tumor libraries in the tissue of interest compared to normal libraries. However, the Examiner suggests that it is unclear what 5H stands for in the data table at page 119-120 and whether prostate means that the sample was taken from a diseased or healthy patient, whether diseased and normal samples were expressed and then compared against one another, how many patients these results stem from, and what the source of the nucleic acids is (e.g. cell culture or tumor). The Examiner also suggests that specification is silent with respect to any potential nucleic acids that fall within claim 1(c) or 1(d). These claims had also been rejected under 35 U.S.C. § 112, first paragraph, for lack of utility, as the Examiner suggests that it would require undue experimentation for those skilled in the art to determine how to use the claimed

invention.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that the specification is unclear with respect to the source of tissue of the nucleic acid sequence of SEQ ID NO:42 or 43 and the level of expression of SEQ ID NO:42 or 43 in cancer vs. normal tissue. The instant specification states at page 119, lines 23 through 26 that to qualify as a CLASP 5 candidate, a gene must be differentially expressed in tumor libraries in the tissue of interest compared to normal libraries for all tissue. Thus, this teaching makes clear that the source of the tissue in which differential expression was observed was tumor tissue of interest and that this differential expression was compared to normal tissue. As made clear throughout the rest of the specification the tumor tissue of interest is prostate cancer tissue. Further, as taught at page 119, lines 9-15, differential expression significance was calculated with rigorous statistical significant testing taking into account variations in sample size and relative gene abundance in different libraries and within each library. Accordingly, the Examiner's basis for this rejection for lack of utility of claims 1-5, 7, 8, 15 because of a questionable tissue source and statistical

significance of the identified CLASP5 markers is flawed.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:42 or 43 as having differential expression in prostate cancer tissue constitutes a pharmacological activity relevant to the asserted use as a diagnostic for prostate cancer, thus satisfying the utility requirement with respect to these nucleic acid molecules.

Further, Applicants respectfully disagree with the Examiner's suggestion that the specification is "silent with respect to any potential nucleic acids that fall within claims 1(c) or (d)." Contrary to the Examiner's suggestion the specification provides detailed teachings of nucleic acid molecules meeting the limitations of claim 1(c) and claim 1(d) at pages 31-40. Further, MPEP § 2107.03 and the courts are quite clear, evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility is routinely supportive of an assertion of therapeutic utility for the structurally similar compound. Applicants have demonstrated

herein the pharmacological utility of SEQ ID NO:42 and 43. Further demonstration of utility of structurally similar compounds to SEQ ID NO:42 and 43 such as set forth in parts (c) and (d) of claim 1 is therefore not required.

Withdrawal of these rejections under 35 U.S.C. § 101 and §112, first paragraph, is respectfully requested in light of the claim amendments and the above remarks.

VI. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

In particular, the Examiner suggests that claims reciting "comprising", "a" nucleic acid of SEQ ID NO:42 or 43, "at least 60% sequence identity" or nucleic acids that "selectively hybridize" to a nucleic acid that encodes SEQ ID NO:96 or "a" nucleic acid of SEQ ID NO:42 or 43, are inclusive of sequences from other species, mutated sequences, allelic variants, full length genes, genomic DNA, for example, all which have different functions than that of the nucleic acid in SEQ ID NO:96, while the specification only teaches SEQ ID NO:42 or 43.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to clarify that the nucleic acid molecule is prostate cancer specific and differentially expressed in prostate cancer tissue, thus clarifying that the nucleic acid molecules have a similar function. Support for this amendment is provided in the specification for example in Example 1. Further, Applicants have amended part (c) of claim 1 to specify conditions of selective hybridization as taught at page 14-16 of the specification. Applicants have also amended part (d) of claim 1 in accordance with teachings at pages 32-33 of the specification to state that the nucleic acid molecule has at least 90% sequence identity over its entire length to the nucleic acid molecule encoding SEQ ID NO:96 or SEQ ID NO:42 or 43.

Further, Applicants respectfully direct the Examiner to pages 13-16 and Example 1 of the specification wherein detailed methodologies for ascertaining sequences which meet the structural and functional limitations of the instant amended claims are set forth. It is respectfully pointed out that such methods for assessing percent sequence identity and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are also performed

routinely by those skilled in the art. Thus, upon discovery of the instant claimed nucleic acid sequence of SEQ ID NO:42 or 43 and their differential expression in prostate tumor tissues, Applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon these reference sequences. Further, the instant specification and its teachings clearly place the public in possession of these sequences as well.

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

VII. Rejection of Claims 1-2 and 4-5 under 35 U.S.C. § 102(a)

Claims 1-2 and 4-5 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Shimkets et al. (WO 00/58473). The Examiner suggests that Shimkets teaches SEQ ID NO:4273, which is 62.5% identical to SEQ ID NO:42 and has a best local similarity of 93.7% identity to SEQ ID NO:42. Further, the Examiner suggests that SEQ ID NO:4273 of Shimkets is 57.9% identical to SEQ ID NO:43 and has a best local similarity of

93.6% identity to SEQ ID NO:43. Thus, the Examiner suggests that since the claims encompass nucleic acids comprising "a" nucleic acid of SEQ ID NO:42 or 43 which includes portions of SEQ ID NO:42 or 43 of any length, Shimkets anticipates the claim. Further, the Examiner suggests that Shimkets teaches the nucleic acid is from a cDNA or genomic DNA, is a mammalian nucleic acid, as well as vectors, hosts cells and methods of producing a polypeptide. The Examiner suggests that Shimkets also teaches a kit comprising means for determining the presence of the claimed nucleic acids.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that by the phrase "a nucleic acid of SEQ ID NO:42 or 43" it is meant to include portions of SEQ ID NO:42 or 43 of any length. Applicants used the term "a" for antecedent basis reasons as this is the first time the nucleic acid of SEQ ID NO:42 or 43 was referred to in the claim.

In an earnest effort to advance the prosecution of this case, however, Applicants have amended claim to remove the phrase "a nucleic acid molecules of SEQ ID NO:42 or 43" instead merely stating that the nucleic acid molecule comprises SEQ ID NO:42 or 43. Thus, claim 1 as amended is drawn to an isolated prostate

cancer specific nucleic acid molecule comprising (a) a nucleic acid sequence encoding SEQ ID NO: 96; (b) SEQ ID NO: 42 or 43; (c) a nucleic acid molecule that selectively hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b); or (d) a nucleic acid molecule having at least 90% sequence identity over its entire length to the nucleic acid molecule of (a) or (b).

Shimket et al. does not teach nucleic acid sequences meeting the limitations of these claims and thus cannot anticipate the claims as amended.

Withdrawal of this rejection is therefore respectfully requested.

VIII. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 102(a)

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Faris et al. (U.S. Pub. No. US2002/0150972). The Examiner suggests that Faris et al. teach SEQ ID NO:1, which is 86.7% identical to the nucleic acid that encodes SEQ ID NO:96. Further, the Examiner suggests that Faris

teaches that the nucleic acid is a cDNA or genomic DNA and that the nucleic acid is mammalian, as well as vectors, host cells and methods of producing a polypeptide. The Examiner also suggests that Faris teaches a kit comprising means for determining the presence of the claimed nucleic acids.

Applicants respectfully traverse this rejection.

It is respectfully pointed out that contrary to the Examiner's suggestion, SEQ ID NO:1 of Faris et al. does not encode SEQ ID NO:96 as claimed. As shown by the sequence alignment provided by the Examiner, the are large regions of disparity between the encoded proteins.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to clarify that a nucleic acid molecule must having at least 90% sequence identity over its entire length to the nucleic acid molecule encoding SEQ ID NO:96 or SEQ ID NO:42 or 43. Support for this amendment is provided in the specification at page 32, line 12 through page 33, line 16.

As Faris does not teach a nucleic acid molecule with these characteristics it cannot anticipate claim 1 as amended nor claims which depend therefrom.

Withdrawal of this rejection under 35 U.S.C. § 102(a) is

therefore respectfully requested.

IX. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell

Kathleen A. Tyrrell
Reg. No. 38,350

Date: May 3, 2004

LICATA & TYRRELL P.C.
66 E. Main Street
Marlton, New Jersey 08053
(856) 810-1515